510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K082683.

DEC - 8 2009

SUBMITTER BY	Standard Diagnostics, Inc.
(Head Office)	156-68 Hagal-dong, Giheung-gu, Yongin-si, Kyonggi-do, Korea
(Manufacturing Site)	C-4th&5th Floor Digital Empire Building 980-3, Yeongtong-dong Yeongtong-gu Suwon-si, Kyonggi-do Korea
(PHONE)	82-31-899-9700
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CONTACT PERSON

(NAME)	William Greenrose
(PHONE)	603 369 3550
(FAX)	603 369 3562

DATE OF SUMMARY April 21, 2008

DEVICE NAME

(Proprietary Name)	SD CHECK GOLD
(Common Name)	Blood Glucose Monitoring System
(Regulation Number)	21 CFR §862.1345
(Classification Name)	Glucose Test System
(Product Code)	NBW
(Subsequent Product Code)	CGA / JJX
(Regulatory Class)	II

PREDICATE DEVICES

	Predicate Device 1	Predicate Device 2
(510(k) Number)	K032552	K024194
(Device Name)	ACCU-CHEK ADVANTAGE SYSTEM	ONE TOUCH® Ultra®
(Submitter by)	Roche Diagnostics Corporation	Lifescan, Inc.

DEVICE DESCRIPTION

SD CHECK GOLD blood glucose system is applicable to monitor blood glucose in capillary whole blood.

SD CHECK GOLD blood glucose monitoring system is comprised of the following.

- SD CHECK GOLD blood glucose meter
- SD CHECK GOLD blood glucose test strip
- SD CHECK GOLD control solution
- SD CHECK GOLD check strip

A drop of blood sample from the finger prick works with glucose oxidase and the mediators in the test strip to make a small electric current proportional to the glucose concentration in the blood. The meter reads the current and displays the blood glucose result equivalent to the current.

INDICATION FOR USE

SD CHECK GOLD Blood glucose monitoring system is indicated for monitoring glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm.

SD CHECK GOLD meter must be used with SD CHECK GOLD blood glucose test strip and SD CHECK GOLD control solutions.

The SD Check Gold control solutions Level M and Level H are for use with SD Check Gold test system as quality controls to verify the accuracy of blood glucose test results.

Testing is done outside the body (in vitro diagnostic use).

This system is indicated for home (over-the-counter; OTC) by person with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

This system should not be used for the screening or diagnosis of diabetes or for testing newborns.

COMPARISION TO PREDICATE DEVICE

The SD CHECK GOLD blood glucose monitoring system of Standard Diagnostics, Inc. is substantially equivalent to the current legally marketed ACC-CHEK Advantage System of Roche Diagnostics Corp and ONE TOUCH® Ultra® of Lifescan, Inc.

Features	Details
Intended use	For self-testing blood glucose using capillary whole blood
Detection Method	Amperometry
System Verification	Control material to check the meter and test strip.
Function	Memory and Average of the test results
Power	One battery (CR 2032 type)

CONCLUSION

The SD CHECK GOLD blood glucose monitoring system is substantially equivalent to predicated ACC-CHEK Advantage System (K032552) of Roche Diagnostics Corp and ONE TOUCH® Ultra®(K024194) of Lifescan, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Standard Diagnostics, Inc.
c/o Mr. William Greenrose
Q Serve America, Inc.
220 River Road
Claremont, NH 03743-0900

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

DEC - 8 2009

Re: k082683
Trade/Device Name: SD Check Gold Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: December 2, 2009
Received: December 4, 2009

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K082683

Device Name SD CHECK GOLD blood glucose monitoring system

INDICATIONS FOR USE

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Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082683